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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,623

07/11/2005

Robert Johan Joseph Hageman

0012/73640/NHZ

7309

7590 12/24/2008  
Cooper & Dunham  
1185 Avenue of the America  
New York, NY 10036

EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/518,623	<b>Applicant(s)</b> HAGEMAN ET AL.	
	<b>Examiner</b> SATYANARAYANA R. GUDIBANDE	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 18-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group I invention (claims 1, 18-25) and election of caseinates from milk as the preferred species of protein (claim 1); guanidine acetic acid as the preferred species of glycoamine (claim 1) ; folic acid as the preferred species of vitamin (claim 21); maltodextrin as the preferred species of food grade carbohydrate (claim 22); magnesium as the preferred species of mineral (claim 24); powder as the preferred form of composition (claim 25); and neurological disorders as the preferred form of disorder (claim 33) in the reply filed on 12/27/07 is acknowledged. The traversal arguments were answered in the office action dated 3/4/08.

Applicant's amendment to claims in the response filed on 8/7/08 has been acknowledged.

Claims 1 and 18-33 are pending.

Claims 26-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/27/07.

Claims 1, 18-25 are examined on the merit.

Any objections and/or rejections made in the office action dated 3/4/08 and not specifically mentioned here are considered withdrawn.

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***Withdrawn Rejections***

Applicant's arguments see page 7-9, filed 8/7/08, with respect to 35 USC 102(b) rejection as being anticipated by Vincent (US 4148912) have been fully considered and are persuasive. The rejection of claims 1, 18, 19 and 22-25 has been withdrawn.

***Maintained Rejections***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 18-25 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 4,582,807 issued to Veeraraghavan in light of the information available from website <http://www.scientificpsychic.com/fitness/carbohydrates.html>. The rejection has been modified to address the amendments to claims 18 and 19. Response to applicant's arguments appears at the end of the reiterated rejection.

In the instant application, applicants claim a nutritional or pharmaceutical composition comprising of L-serine and glycoamine and the composition is free of glycine.

Veeraraghavan discloses a composition for a medium (a nutritional broth for mycobacteria) for the cultivation of mycobacteria that comprises of serine (column 11, line 10), glycoamine (column 11, lines 16 and 17). The composition is devoid of glycine and hence meets the limitation of 1 and 18 (claim 1 of the cited reference). The composition of discloses

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that it contains 350-420 mg of glycocytamine and 3.4-4.1 g of amino acid serine. This indicates that the amount of glycocytamine is ~10% (also equal to 1 times that of serine) compared to serine and hence meets the limitation of claim 18. The composition also comprises of creatinine (column 11, line 15) and hence reads on claim 19. The cited reference also discloses amino sugars such as glucosamine, arabinose, galactose, mannose, d-ribose and mixtures thereof (column 11, lines 21-23) that reads on the instant claim 22. Since the sugar glucosamine and mannose, etc., are an aldehyde sugars (see information available on website:

[‘http://www.scientificpsychic.com/fitness/carbohydrates.html’](http://www.scientificpsychic.com/fitness/carbohydrates.html)), it meets the limitation of claim 23. The website reference is post dated to the effective filing date of the instant application. "In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism." See MPEP 2124. The reference of Veeraraghavan also teaches the presence of minerals such as magnesium (column 4, line 41) and reads on the instant claim 24. Veeraraghavan also teaches the vitamins in the composition specifically folic acid (column 4, line 28) and hence meets the limitation of claim 21. The composition is in sterile water and hence meets the limitation of instant claim 25.

Therefore, the cited reference of Vincent anticipates the claims 1, 18, 19 and 21-24 of the instant invention.

### ***Response to Arguments***

1. Applicants argue that Veeraraghavan discloses a medium for mycobacteria cultivation and not a nutritional or pharmaceutical composition.

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2. Applicants argue that the culture medium lists extensive list of components that includes serine and glycocyamine but it does not teach that serine and glycocyamine should be administered conjunctively to derive the benefit.

3. Applicants argue that Veeraraghavan explicitly states that the culture medium is devoid of protein and hence the feature of the instant invention is not found in the teachings of Veeraraghavan.

Applicant's arguments filed 8/7/08 have been fully considered but they are not persuasive.

1. Applicants arguments are not persuasive because, culture medium is a nutritional composition helps the bacteria to grow. The definition from the website:

<http://en.wiktionary.org/wiki/nutritional>, for the term 'nutritional' is defined as "Of, pertaining to, or providing nutrition". Hence the culture medium provides nutrition for the bacteria to grow. Moreover, the medium of Veeraraghavan is prepared in sterile water (column 11, line 42) and a ph of the medium is in the range 7.0-7.2 (column 3, line 18-19). Hence the composition is suitable to be a pharmaceutical composition.

2. Instant claims are drawn to a nutritional or pharmaceutical composition with the transitional phrase "comprising". Hence, the composition may contain any number of additional components above the required desired components "serine and glycocyamine". Since the serine and glycocyamine is present in the composition, when administered it is administered conjunctively.

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3. Although, Veeraraghavan discloses a composition that is devoid of protein, the instant claims only requires the presence of L-serine that is selected from the Markush group. Also, the specification as disclosed on page 9, lines 26-29, defines the protein fraction containing L-serine as “it is meant protein containing L-serine **but also** L-serine containing component selected from L-serine, equivalents thereof and mixtures thereof”. Hence, L-serine reads on the instant claims.

*New grounds of rejection*

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim has been amended to recite that the “molar amount of energy metabolism precursor lies within the range of from 0.1 to 10 times the excess of L-serine minus glycine.”

*Lack of Ipsis Verbis Support*

The specification lacks any Ipsis Verbis support that would support the limitation that “molar amount of energy metabolism precursor lies within the range of from 0.1 to 10 times the excess of L-serine minus glycine”. The specification discussing support for the limitation states

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“the molar amount of "energy metabolism precursor" to be daily administered lies within the range of from 0.1-10 time the excess of L-serine **versus** glycine, and more preferably lies within the range of from 0.2-4 times the excess of L-serine **versus** glycine” (page 13, lines 7-10).

### ***Lack of Implicit Support***

It is acknowledged that there is it should be noted, that exact terms need not be used *in haec verba* to satisfy the written description requirement of the first paragraph of 35 U.S.C. 112.

Newly added claims or amendment can be supported by implicit, or inherent disclosure.

However, the specification also lacks any implicit or inherent disclosure for the limitation “molar amount of energy metabolism precursor lies within the range of from 0.1 to 10 times the excess of L-serine **minus** glycine.” The specification discloses the term “**versus**” compared to the term “**minus**” recited in the claim 18. The two terms have entirely different meaning and alters the scope of the recited claim. The term “versus” has the meaning “against” or “opposed to” according to the website:

“<http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861733906>”.

Meaning of the term “minus” according to the website: “<http://en.wiktionary.org/wiki/Minus>”, is “a negative quantity”.

Hence the specification as disclosed does not support the change in the scope of the invention as recited in the amended claim.

In conclusion, the specification does not provide reasonable support to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as amended.



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Applicant's amendment to claim 18 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/  
Examiner, Art Unit 1654

/Andrew D Kosar/  
Primary Examiner, Art Unit 1654